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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,123	04/24/2001	Shigeru Iida	001560-397	2738
	7590	11/13/2003	EXAMINER	
Ronald L. Grudziecki Burns Doane Swecker & Mathis PO Box 1404 Alexandria, VA 22313-1404			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/830,123	Applicant(s) IIDA ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-22 and 31-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-22 and 31-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed July 2, 2003 has been entered.

Claims 9-10, 23-30 and 47-51 are cancelled.

Claims 1-6, 11-12, 15-18 and 31-46 are currently amended.

Claims 1-8, 11-22 and 31-46 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1, 3-8, 11-14, 16-18, 20-22, 32-34, 36-38, 40-42 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 2, 2003.

Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention is described because the novel sequence of SEQ ID NO:2 is disclosed. Applicant argues that by having this information one skilled in the art would recognize the structure of modified sequences, as the ability to determine which substitutions could be made in SEQ ID NO:2 without changing the properties of the encoded protein is within the abilities of one skilled in the art (reply pages 10-11).

The rejection is maintained because the rejected claims make no reference to the structure of SEQ ID NO:2. The rejection is also maintained because the disclosure of the single novel sequence of SEQ ID NO:2 does not describe the structure of all Na⁺H⁺ antiporter genes as claimed. While one skilled in the art has the ability to determine what constitutes a conservative amino acid change, the disclosure of the single novel sequence does not provide sufficient description for one skilled in the art to recognize which amino acid of SEQ ID NO:2 could be substituted without changing the properties of the encoded protein. The disclosure of the single novel sequence also does not provide sufficient description for one skilled in the art to recognize which amino acid of SEQ ID NO:2 could be added and/or deleted without changing the properties of the encoded protein.

Claims 1, 3-8, 11-14, 16-18, 20-22, 32-34, 36-38, 40-42 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding an amino acid sequence of SEQ ID NO:2 and methods of transforming plants and plant cells using said isolated nucleic acid, does not reasonably provide enablement for other isolated nucleic acids or methods of using other isolated nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed January 2, 2003.

Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that it would not require undue experimentation to modify SEQ ID NO:2 by addition, substitution or deletion, or to obtain sequences that hybridize to SEQ ID NO:2, as the techniques by which this could be accomplished were well known in the art at the time of filing. Applicant further argues that the techniques disclosed in the specification would enabled one skilled in the art to test modified sequences to determine their effect on vacuolar pH and flower color (pages 11-12).

The rejection is maintained because the rejected claims 1, 7-8 and 11-14 make no reference to the use of SEQ ID NO:2. The rejection is also maintained because the specification does not provide sufficient guidance for one skilled in the art to modify SEQ ID NO:2 by addition, substitution or deletion without undue experimentation, or to obtain sequences that hybridize to SEQ ID NO:2 without undue experimentation, as the specification provides no guidance with respect to which amino acids may be added, substituted or deleted in SEQ ID NO:2 without changing the properties of the encoded protein, or with respect to which sequences hybridizing to a nucleic acid encoding SEQ ID NO:2 would encode a protein having the same activity as SEQ ID NO:2. Without such guidance one skilled in the art would have to resort to testing every modification of SEQ ID NO:2 in order to determine which changes would affect the function of the protein and which would not. Without such guidance one skilled in the art would also have to resort to testing every sequence obtained under a variety of hybridization conditions in order to determine which sequences would encode a protein having the same activity as SEQ ID NO:2. While such trial and error testing would employ techniques that are within the abilities of the skilled artisan, such trial and error testing constitutes undue

experimentation in the absence of guidance for discriminating between operative and inoperative embodiments that fall within the scope of the claims.

Claim 6, and claims 18, 22, 30, 34, 38, 42 and 46 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “ a stringent condition”, for the reasons of record set forth in the office action mailed January 2, 2003.

Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that the rejected language is sufficiently clear, and points in support of this assertion to a claim employing the rejected language in U.S. Patent No. 5,910,627. Applicant further argues that the rejected language would be clear to one skilled in the art by reference to the example set forth in the specification (reply page 13).

The rejection is maintained because the example set forth in the specification does not specifically limit the phrase “ a stringent condition” recited in the rejected claim. With respect to “ a stringent condition” being employed in a claim in U.S. Patent No. 5,910,627, the Examiner maintains that this point is not germane to the instant rejection, because each application is examined on its own merits, and because no word or phrase is per se definite or indefinite.

Claims 11-12 and 31-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-12 and 31-38 are indefinite in the recitation of “a progeny of said plant in which said gene has been introduced” and “a progeny of said plant in

which said nucleic acid sequence has been introduced”. Applicant’s reply at page 14 indicates that the claims were amended to indicate that the progeny or tissue comprise the gene or isolated nucleic acid that was introduced into the transgenic parent plant, but the claim language indicates that “said gene” or “said nucleic acid sequence” has been introduced into “said plant” rather than into “a progeny”.

Claim Rejections - 35 USC § 102

Claims 1, 3, 6-8, 11-14, 16, 18, 20, 22, 32, 34, 36, 38, 40, 42, 44 and 46 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chuck et al. (US Patent 5,910,627 issued June 8, 1999), for the reasons of record set forth in the office action mailed January 2, 2003.

Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn because Chuck et al. describes the Ph6 gene, which encodes a transcriptional regulator protein, rather than a Na⁺H⁺ antiporter gene as claimed (reply page 15).

The rejection is maintained because the rejected claims still recite no structural limitations that distinguish the claimed Na⁺H⁺ antiporter gene from the Ph6 gene taught by Chuck et al.

Claims 1, 3-8, 16-18 and 20-22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gaxiola et al. (Proc. Natl. Acad. Sci. USA, Vol. 96, pages 1480-1485, February

1999, Applicant's IDS), for the reasons of record set forth in the office action mailed January 2, 2003.

Applicant's arguments filed July 2, 2003 have been fully considered but they are not persuasive.

Applicant argues that the rejection should be withdrawn because Gaxiola et al. does not disclose or suggest a gene or nucleic acid sequence encoding a protein that will alter flower color as instantly claimed (reply page 15).

The rejection is maintained because the protein encoded by the nucleic acid taught by Gaxiola et al. would inherently have an activity of altering flower color, as both the protein encoded by the nucleic acid taught by Gaxiola et al. and the protein encoded by the nucleic acid disclosed by Applicant exhibit a Na⁺H⁺ antiporter function. Furthermore, the rejected claims recite no structural limitations that would distinguish the claimed Na⁺H⁺ antiporter gene from a Na⁺H⁺ antiporter gene encoding a protein that would not function to alter flower color.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 2, 15, 19 and 39 are allowed.

Claims 1, 3-8, 11-14, 16-18, 20-22, 31-38 and 40-46 are rejected.

Claims 2, 15, 19, 31, 35, 39 and 43 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleic acid encoding an amino acid sequence of SEQ ID NO:2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

1638

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